

REPUBLIC OF SOUTH AFRICA
SPOOR AND FISHER
REVENUE
18.6.96
R 13500
INKOMSTE
REPUBLIEK VAN SUID AFRIKA
The grant of a patent hereby requested by the undermentioned applicant on the basis of the accompanying application for a patent.
OFFICIAL APPLICATION No.

REPUBLIC OF SOUTH AFRICA
REVENUE
FORM P.1
18.6.96
R 24200
INKOMSTE
REPUBLIEK VAN SUID AFRIKA
S & F REFERENCE

21 01 965149

JP/D1372

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TITLE OF INVENTION
54 VITAMIN AND NUTRIENT SUPPLEMENT COMPOSITIONS

THE APPLICANT CLAIMS PRIORITY AS SET OUT ON THE ACCOMPANYING FORM P.2. THE EARLIEST PRIORITY CLAIMED IS:
COUNTRY: ZA NUMBER: 95/2225 DATE: 17.03.95

THIS APPLICATION IS FOR A PATENT OF ADDITION TO PATENT APPLICATION NO.

21 01

THIS APPLICATION IS A FRESH APPLICATION IN TERMS OF SECTION 37 AND IS BASED ON APPLICATION NO.

21 01

THIS APPLICATION IS ACCOMPANIED BY:

- ☒ 1. Two copies of a complete specification of 21 pages.
- ☐ 2. Drawings of ... sheets.
- ☒ 3. Publication particulars and abstract (Form P.8 in duplicate).
- ☐ 4. A copy of Figure ... of the drawings (if any) for the abstract.
- ☐ 5. An assignment of invention.
- ☐ 6. Certified priority document(s).
- ☐ 7. Translation of the priority document(s).
- ☐ 8. An assignment of priority rights.
- ☒ 9. A copy of the Form P.2. and the specification of S.A. Patent Application No. 95/2225
- ☐ 10. A declaration and power of attorney on Form P.3.
- ☐ 11. Request for ante-dating on Form P.4.
- ☐ 12. Request for classification on Form P.9.
- ☐ 13.

74 ADDRESS FOR SERVICE: SPOOR AND FISHER, SANDTON

Dated : 18TH JUNE 1996

SPOOR AND FISHER
APPLICANTS PATENT ATTORNEYS

RECEIVED
1995-06-18
REGISTRAR OF PATENTS
REGISTRATEUR VAN PATENTE, MODELLE, HANDELSMERKE EN OUTFEERSREK

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978**COMPLETE SPECIFICATION**

(Section 30(1) - Regulation 28)

OFFICIAL APPLICATION NO.

21	01	365149
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LODGING DATE

22	18.06.96
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INTERNATIONAL CLASSIFICATION

51	A61K;A23K;A23J;A23L
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TITLE OF INVENTION

54	VITAMIN AND NUTRIENT SUPPLEMENT COMPOSITIONS
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BACKGROUND OF THE INVENTION

THIS invention relates to vitamin and nutrient supplement compositions.

It is known that by supplementing the diet of domestic birds, such as pigeons and parrots, with trace elements and β carotene (pro Vitamin A) and certain amino acids, their stamina, immune systems and general well being can be enhanced. In particular, these substances have been found to assist in fighting adenovirus infections and other viral infections. However, β carotene is sensitive to heat and light oxidation and is oily and therefore difficult to administer.

SUMMARY OF THE INVENTION

According to the invention a first vitamin and nutrient supplement composition comprises:

an antioxidant;
a carotenoid; and
gluten.

Preferably, the carotenoid is β carotene (pro Vitamin A) or a derivative or analog thereof.

Preferably, the gluten is corn gluten.

The corn gluten will generally contain a quantity of corn syrup.

The antioxidant is preferably Vitamin E (dl α Tocopherol).

- The composition is preferably in a powder or granule form.

The composition may also comprise Vitamin C.

According to another aspect of the invention a medicament comprises a composition of the invention and an opaque or dark container containing the composition.

According to another aspect of the invention a second vitamin and nutrient supplement composition comprises:

starch;
l-methionine;
a magnesium salt;
a member of the Vitamin B complex;
a pyridine derivative having Vitamin B6 activity;
Vitamin B12;
glycine; and
an antifungal agent.

The member of the Vitamin B complex is preferably folic acid.

The pyridine derivative having Vitamin B6 activity is preferably pyridoxine (Vitamin B6).

The starch is preferably potato starch.

The magnesium salt is preferably magnesium chloride.

The composition may also comprise Vitamin C.

According to another aspect of the invention a third vitamin and nutrient supplement composition comprises a combination of the first and second compositions of the invention, preferably in a mass ratio of 1:1.

According to another aspect of the invention a method of preparing the first vitamin and nutrient supplement composition comprises the steps of:

forming a solution of the antioxidant in a solvent;
adding the carotenoid to the solution; and

adding the balance of the components and allowing the mixture to dry.

The solvent is preferably acetone or ethanol.

The dried mixture is preferably stored in an opaque or dark airtight container.

According to another aspect of the invention a method of preparing the second vitamin and nutrient supplement composition comprises the steps of:

- combining the starch with water;
- adding a further amount of heated water to the mixture;
- adding the balance of the components to the mixture; and
- forming a dough.

The heated water is preferably at a temperature of at least 80°C and more preferably at boiling point.

According to another aspect of the invention a method of preparing a third vitamin and nutrient supplement composition comprises the step of combining the first vitamin and nutrient supplement composition in a dry powdered form with the second vitamin and nutrient supplement composition in a dry form.

The method may also include the step of crumbling and air drying the dough.

According to another aspect of the invention there is provided use of a

vitamin and nutrient supplement composition of the invention in a method of preventing and treating viral infection in birds and other animals.

The bird may be a pigeon and the viral infection may be an adenovirus infection.

The animal may be a human and the viral infection may be HIV infection.

The animal may be a dog and the viral infection may be parvovirus infection.

The animal may be a cat and the viral infection may be feline aids infection.

According to another aspect of the invention there is provided use of a first or third nutrient supplement composition of the invention in a method of enhancing the absorption of β carotene or a derivative or analog thereof and an antioxidant by an animal.

According to another aspect of the invention there is provided use of a vitamin and nutrient supplement composition of the invention in a method of boosting the immune system of an animal.

According to another aspect of the invention there is provided use of a vitamin and nutrient supplement composition of the invention in a method of increasing endurance and physical performance in an animal.

The animal may be a human or a horse or a bird.

According to another aspect of the invention there is provided use of a

vitamin and nutrient supplement composition according to the invention in the method of making a medicament for use in treating or preventing a viral infection in an animal.

According to another aspect of the invention there is provided use of a vitamin and nutrient supplement composition according to the invention in a method of making a medicament for use in a method of enhancing the absorption of β carotene or a derivative or analog thereof by an animal.

According to another aspect of the invention there is provided use of a vitamin and nutrient supplement composition according to the invention in a method of making a medicament for use in boosting the immune system in an animal.

According to another aspect of the invention there is provided use of a vitamin and nutrient supplement composition according to the invention in a method of making a medicament for use in increasing endurance and physical performance in an animal.

The composition may be administered to the animal in an amount of about 0.5g to about 1g per kg of body weight.

DESCRIPTION OF A PREFERRED EMBODIMENT

The vitamin and nutrient supplement compositions contain a unique mixture of amino acids, vitamins and other supplements. They have been found to be particularly useful in birds in boosting their immune system and in

providing resistance to viral infections, particularly adenovirus infections. The first and third compositions contain a relatively high proportion of β carotene, which is an oily fluid. β carotene (pro Vitamin A) is known to be sensitive to heat and light oxidation. It must therefore be administered with an antioxidant. The best antioxidant is tocopherol (Vitamin E) which is also an oily substance. Although this mixture can be administered directly, in the form of a soft gelatine capsule, it is difficult and it is suspected that much of the β carotene administered in this way is not utilised.

The difficulty with the β carotene and tocopherol is their oily nature. However, it has been found that by forming a solution of these two components in acetone or ethanol and then adding this mixture to corn gluten, a convenient, easy to handle granular mixture is formed. The corn gluten, which is difficult to digest and which consists mainly of indigestible protein (gluten) and corn syrup, acts as a carrier as well as a slow release dosage form. The porous structure of the corn gluten absorbs the acetone or ethanol and the dissolved β carotene. The acetone or ethanol then evaporates leaving the β carotene and Vitamin E absorbed on the gluten. When ingested, it ensures a slow release of the β carotene and other essential vitamins. The absorption into the gluten also protects the β carotene from light oxidation.

The corn gluten itself is also an important source of trace elements, such as iron, copper, manganese, zinc and selenium, and the administration of these elements together with β carotene and tocopherol has been found to enhance the absorption of the trace elements and the β carotene and tocopherol. In addition the gluten contains high proportions of some amino acids, as set out in Table 1, in particular glutamic acid and leucine. It also contains

additional vitamins, particularly choline and inositol. These amino acids, trace elements and vitamins have a positive effect on the absorption and metabolism of the β carotene and tocopherol. The type of corn gluten used in the present compositions is sold under the name PRIMAGLUTEN™. This corn gluten contains some corn syrup.

A typical formulation for the first composition of the invention is:

<u>INGREDIENTS</u>	<u>FORMULATION</u>
Corn gluten	1000g
Vitamin E	45g
β Carotene	30g
Acetone (ml)	250g

A typical formulation for the second composition of the invention is:

<u>INGREDIENTS</u>	<u>FORMULATION</u>
<i>l</i> -Methionine	380, 3g
Magnesium chloride	117g
Folic acid	1.5g
Vitamin B6 (pyridoxine)	1.2g
Vitamin B12	0.037g
Starch	0.004g
Glycine	500g
Mycocurb™	5g
Water	1800 ml

A typical dosage of the second composition is 0.5 g per kilogram of live body mass for birds and animal species. The formulation has been found to have immune stimulating properties and to increase endurance in birds such as racing pigeons and also to decrease their race recovery time.

This composition is either administered in a dry powder form or in a crumb form. The crumbs are produced as follows:

100 g of potato starch is mixed with 100 ml of cold water (this prevents the starch from clotting);

this mixture is added to 1.25 l of boiling water and stirred;

the starch becomes thick and viscose and has good binding properties;

this is mixed with 5 kg of the starch/amino acid/vitamin/mineral acid mix which forms a dough which can be crumbed and hardened by air drying.

The first composition containing β carotene, tocopherol and corn gluten can be mixed with the second composition containing starch, amino acids, minerals and vitamins in a ratio of 1:1 to form the third, and most effective, composition of the invention. The acetone and most of the water will be removed before mixing takes place. In this combination the second composition does not contain Mycocurb and is not formed into a dough and granulated. Instead, a dry powdered form of the first composition is mixed with a dry powdered form of the second composition to form the third composition. This combination has been found to enhance greatly the

immune system. A typical dose is 1 g per kg of body weight and this dosage was found to help pigeons with adenovirus infection to recover within 10 days.

When the compositions of the invention are intended for human consumption, they may be prepared and sold in the form of energy bars.

The results on birds are encouraging and would seem to indicate that the composition could have similar anti-viral properties in other animals, including humans, particularly people with HIV infections and dogs with parvovirus infections and cats with feline aids. As mentioned above for the second composition, it has been found to increase endurance in endurance athletes, such as racing pigeons and to shorten the recovery time after racing. It should have the same effect in humans, such as long distance athletes, weight lifters and power lifters and animals, such as horses, particularly racehorses.

Without wishing to be bound by theory, it is postulated that the compositions of the invention, alone or in combination, increase the methylation capacity of the animal body. This stimulates and normalises the immune system and also stimulates the production of glutathione, a compound which has anti-viral properties. The composition has, so far, only been tested on birds. Birds are known to produce their own Vitamin C and it is postulated that when the combination is given to other animals, it will be necessary to add Vitamin C to the combination in an amount of from 300 to 500 mg per dose.

TABLE 1

NUTRIENT COMPOSITION OF CORN GLUTEN
(typical values)

	Corn Gluten Feed 21% Protein	Corn Gluten Meal 60% Protein
AMINO ACIDS (% in Feedstuffs)		
Alanine	1.5	5.2
Arginine	1.0	1.9
Aspartic Acid	1.2	3.6
Cystine	0.5	1.1
Glutamic Acid	3.4	13.8
Glycine	1.0	1.6
Histidine	0.7	1.2
Isoleucine	0.6	2.3
Leucine	1.9	10.1
Lysine	0.6	1.0
Methionine	0.5	1.9
Phenylalanine	0.8	3.8
Proline	1.7	5.5
Serine	1.0	3.1
Threonine	0.9	2.0
Tryptophan	0.1	0.3
Tyrosine	0.6	2.9
Valine	1.0	2.7

VITAMINS (mg/lb)

Vitamin A (equiv)*	0	30-65
Beta-Carotene	0	20-30
Choline	1100	1000
Niacin	34	37
Pantothenic Acid	7.8	1.3
Pyridoxine	6.8	2.8
Riboflavin	1.1	1.0
Thiamine	0.9	0.1
Biotin	0.1	0.1
Inositol	2450	860

MINERALS (% in Feedstuffs)

TOTAL ASH (%)	7.8	1.8
Potassium (%)	1.3	0.45
Phosphorus (%)	0.9	0.70
Magnesium (%)	0.42	0.15
Chloride (%)	0.23	0.10
Calcium (%)	0.2	0.02
Sulfur (%)	0.16	0.83
Sodium (%)	0.12	0.03
Iron (ppm)	304	167
Zinc (ppm)	88	42
Manganese (ppm)	22	Trace
Copper (ppm)	9.9	22
Chromium (ppm)	<1.5	<1.5
Molybdenum (ppm)	0.8	0.6

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Selenium (ppm)	0.22	0.66
Cobalt (ppm)	0.09	0

*As retinol (0.15 mg. retinol - 5000 I.U. Vitamin A)

CLAIMS

1. A vitamin and nutrient supplement composition comprising:

an antioxidant;
a carotenoid; and
gluten.
2. A vitamin and nutrient supplement composition according to claim 1, wherein the carotenoid is β carotene (pro Vitamin A) or a derivative or analog thereof.
3. A composition according to claim 1 or claim 2, wherein the gluten is corn gluten.
4. A composition according to claim 3, wherein the corn gluten contains corn syrup.
5. A composition according to any one of claims 1 to 4, wherein the antioxidant is tocopherol.
6. A composition according to claim 5, wherein the antioxidant is dl α tocopherol.
7. A composition according to any one of claims 1 to 6, which is in a powdered or granular form.
8. A vitamin and nutrient composition according to claim 1 also

comprising Vitamin C.

9. A medicament comprising a composition according to any one of claims 1 to 8 and an opaque or dark container containing the composition.
10. A vitamin and nutrient supplement composition comprising:
 - starch;
 - l-methionine;
 - a magnesium salt;
 - a member of the Vitamin B complex;
 - a pyridine derivative having Vitamin B6 activity;
 - Vitamin B12;
 - glycine; and
 - an antifungal agent.
11. A vitamin and nutrient supplement composition according to claim 10, wherein the member of the Vitamin B complex is folic acid.
12. A vitamin and nutrient supplement composition according to claim 10 or 11, wherein the pyridine derivative having Vitamin B6 activity is pyridoxine (Vitamin B6)
13. A composition according to any one of claims 10 to 12, wherein the starch is potato starch.
14. A composition according to any one of claims 10 to 13, wherein the magnesium salt is magnesium chloride.

15. A vitamin and nutrient supplement composition according to any one of claims 10 to 14 also comprising Vitamin C.
16. A vitamin and nutrient supplement composition comprising a combination of a composition according to any one of claims 1 to 8 and a composition according to any one of claims 10 to 15.
17. A composition according to claim 16 comprising a combination of a composition according to claim 1 and a composition according to claim 10 in a mass ratio of 1:1.
18. A method of preparing the vitamin and nutrient supplement composition according to any one of claims 1 to 8 comprising the steps of:
 - forming a solution of the antioxidant in a solvent;
 - adding the carotenoid to the solution; and
 - adding the balance of the components and allowing the mixture to dry.
19. A method according to claim 18, wherein the solvent is acetone or ethanol.
20. A method according to claim 18 or claim 19 also comprising the step of placing the composition in an opaque or dark, airtight container.

21. A method of preparing the vitamin and nutrient supplement composition according to any one of claims 10 to 15 comprising the steps of:

combining the starch with water;

adding a further amount of heated water to the mixture;

adding the balance of the components to the mixture;
and

forming a dough.

22. A method according to claim 21, wherein the heated water is at a temperature of at least 80°C.
23. A method according to claim 22, wherein the heated water is at boiling point.
24. A method according to claim 21 or claim 22 also comprising the steps of crumbling and drying the dough.
25. A method according to claim 24, wherein the dough is air dried.
26. A method of preparing the vitamin and nutrient supplement composition according to claim 16 or claim 17 comprising the steps of combining a composition according to any one of claims 1 to 6 or 8 in a powdered form and a composition according to any one

of claims 10 to 15 in a powdered form.

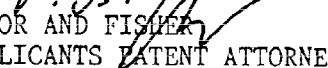
27. Use of a vitamin and nutrient supplement composition according to any one of claims 1 to 17 in a method of preventing and treating a viral infection in an animal.
28. Use according to claim 27 wherein the animal is a bird.
29. Use according to claim 28 wherein the bird is a pigeon.
30. Use according to any one of claims 27 to 29, wherein the viral infection is an adenovirus infection.
31. Use according to claim 27, wherein the animal is a human.
32. Use according to claim 31, wherein the viral infection is HIV infection.
33. Use according to claim 27, wherein the animal is a dog.
34. Use according to claim 33, wherein the viral infection is parvovirus infection.
35. Use according to claim 27, wherein the animal is a cat.
36. Use according to claim 35, wherein the viral infection is feline aids infection.
37. Use of a vitamin and nutrient supplement composition according to

any one of claims 1 to 8 and claim 16 and claim 17 in a method of enhancing the absorption of a carotenoid thereof and an antioxidant by an animal.

- 38. Use of a vitamin and nutrient supplement composition according to any one of claims 1 to 17 in a method of boosting the immune system of an animal.
- 39. Use of a vitamin and nutrient supplement composition according to any one of claims 1 to 17 in a method of increasing endurance and physical performance in an animal.
- 40. Use according to claim 39, wherein the animal is a human, horse or bird.
- 41. Use according to claim 40, wherein the animal is an endurance athlete.
- 42. Use according to claim 41, wherein the animal is a racehorse or racing pigeon.
- 43. Use of a vitamin and nutrient supplement composition according to any one of claims 1 to 17 in a method of making a medicament for use in treating or preventing a viral infection in an animal.
- 44. Use of a vitamin and nutrient supplement composition according to any one of claims 1 to 8 and claim 16 and claim 17 in a method of making a medicament for use in a method of enhancing the absorption of a carotenoid and an antioxidant by an animal.

45. Use of a vitamin and nutrient supplement composition according to any one of claims 1 to 17 in a method of making a medicament for use in boosting the immune system in an animal.
46. Use of a vitamin and nutrient supplement composition according to any one of claims 1 to 17 in a method of making a medicament for use in increasing endurance and physical performance in an animal.
47. Use according to any one of claims 27 to 46, wherein the composition is administered to the animal in an amount of about 0.5g to about 1g per kg of body weight.
48. A composition according to claim 1 substantially as herein described with reference to any one of the illustrative examples.
49. A composition according to claim 10 substantially as herein described with reference to any one of the illustrative examples.
50. A method according to claim 18 substantially as herein described with reference to the illustrative example.
51. A method according to claim 21 substantially as herein described with reference to the illustrative example.

DATED THIS 18TH DAY OF JUNE 1996


SPOOR AND FISHER
APPLICANTS PATENT ATTORNEYS